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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,510	11/26/2003	Aldo P. Ferreira	3673-27	6109

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,510	FERREIA	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11/26/03* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's preliminary amendment filed November 26, 2003 is acknowledged. Claim 1-11 and 14-20 have been cancelled.

Specification Objections

2. The specification is objected to for the following informalities:

page 10 recites "... for example, o petri dish or slide...". It appears that the sentence should recite "...on a petri dish or slide...". Correction is required.

3. The use of the trademarks has been noted in this application. For example see, page 21 or 22. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 12-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising a selective culture medium, does not reasonably provide enablement for a composition comprising a selective culture medium and reactants capable of altering the properties of the medium in a manner as to favor the interaction of the system fiber-microorganism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims broadly encompass a genus of reactants which are capable of altering the properties of the medium in a manner as to favor the interaction system fiber-microorganism. The specification merely states "as an option, it is possible to use reactants that are capable of altering the properties of the culture medium in a manner as to permit that the index of refraction of the subject is better detected" (page 11). The specification teaches that during the lag phase, due to the metabolism of the microorganism, enzymes are released that cause an alteration of the index of refraction and/or the increase in the number of microorganisms in contact with the optical fiber during the log phase turns that medium opaque (page 13). The specification disclosed that these situations cause the intrinsic absorption to suffer alterations (page 13). Example 3 of the specification discloses the growth of microorganisms in a selective culture medium (pages 22-24). In this example, each microorganism was grown in media specific for that organism (e.g. *Staphylococcus aureus* resistant to methicillin grown on Baird-Parker Agar). Each culture of bacteria

was allowed to grow at an appropriate temperature. The instant specification does not disclose the addition of any reactants to the culture media. One skilled in the art would require guidance to make and use the claimed invention commensurate in scope with the claimed invention since the reactants that can be added to the claimed compositions in such a manner to permit better detection of the index of refraction of the subject are not disclosed in the specification.

Factors to be considered in determining whether undue experimentation is required are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

In view of the lack of enablement for the a composition comprising a selective culture medium and reactants capable of altering the properties of the medium in a manner as to favor the interaction other system fiber-microorganism. It is determine that there are limited working examples commensurate in scope with the instant claims and there is limited guidance provided in the specification as to how to make and use the claimed invention. The skilled artisan is forced into undue experimentation to practice (make and use) the invention as is broadly claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 12-13 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language of the claims is not as precise as the subject matter permits such that one would reasonably know the metes and bounds of the claimed subject matter. Correction is required.

a) Claims 12-13 recite "characterized by". It is unclear as to what the applicant is referring?

b) Claims 12-13 recite "capable of". Capable is a potential. The claimed limitation is optional and therefore not positively recited as an actual claim limitation.

c) Claims 12-13 recite "system fiber-microorganism", it is unclear as to what the applicant is referring?

d) Claims 12-13 recite "alteraction", it is unclear as to what the applicant is referring?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following rejections are made because Applicant has not defined the term "reactants that are capable of altering the properties of the medium in manner as to favor the interaction of the fiber-microorganism.

6. Claims 12-13 are rejected under 35 U.S.C. 102(e) as anticipated by Simpson et al. *(U.S. Patent No. 6,117,643, published September 12, 2000).*

Claims 12-13 are drawn to a composition for the use in the detection of microorganisms characterized by comprising a selective culture medium for the microorganisms to be detected and reactants capable of altering the properties of the medium in a manner as to favor the interaction of the system fiber-microorganism.

Simpson et al teach compositions containing one or more fluid or nutrient reservoirs (medium) and one or more microfluidic pumps to provide nutrient means for the bioreporter organisms (e.g. yeast, bacteria or animal cells) used for detecting the concentration of a particular sample (column 2, lines 48-53). Simpson et al teach that

the compositions comprising the nutrient reservoirs are contained with an apparatus for detecting the concentration of a particular sample (column 2, lines 48-53). Simpson et al teach the use of bioreporter organisms that are capable of metabolizing the substance, upon contact with the bioreporter encodes a luminescent reporter molecule (column 2, lines 66-67 and column 3, lines 1-15) which meets the claim limitation "reactants capable of altering the properties of the medium in a manner as to favor the interaction of the system fiber-microorganism". The claim limitation such as "...wherein the alteraction is in the index of refraction of the system" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

7. Claims 12-13 are rejected under 35 U.S.C. 102(b) as anticipated by Findl et al, *(U.S. Patent No. 4,242,447, published December 30, 1990).*

Claims 12-13 are drawn to a composition for the use in the detection of microorganisms characterized by comprising a selective culture medium for the microorganisms to be detected and reactants capable of altering the properties of the medium in a manner as to favor the interaction of the system fiber-microorganism.

Findl et al teach a rapid method of detecting bacteria (see the Title). Findl et al teach a composition comprising bacteria having an enzymic system (reactants) that will react with a fluorescent conjugate to release the fluorescent portion of the molecule (column 4, lines 44-65) which meets the claim limitation "reactants capable of altering the properties of the medium in a manner as to favor the interaction of the system fiber-microorganism". The claim limitation such as "...wherein the alteraction is in the index of refraction of the system" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

8. Claims 12-13 are rejected under 35 U.S.C. 102(b) as anticipated by Burlage et al *(Appl. Biochem. Biotechnol., 45/46:731-740, 1994).*

Claims 12-13 are drawn to a composition for the use in the detection of microorganisms characterized by comprising a selective culture medium for the microorganisms to be detected and reactants capable of altering the properties of the medium in a manner as to favor the interaction of the system fiber-microorganism.

Butlage et al teach using bioluminescent reporter bacteria to detect contaminants in soil samples (page 731). Butlage et al demonstrate that bioluminescent report strains can provide valuable data about the presence and bioavailability of specific contaminants in environmental samples (page 738).Burlage et al teach the addition of xylene to a composition comprising a strain of *Pseudomonas putida* (page 736). Burlage et al teach that the induction of the sample with xylene resulted in a strong bioluminescent response, therefore meeting the claim limitations "...reactants capable of altering the properties of the medium in a manner as to favor the interaction of the system fiber-microorganism." The claim limitation such as "...wherein the alteraction is in the index of refraction of the system" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of Claims

9. No claims are allowed.

Conclusion

10. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Vanessa L. Ford
Biotechnology Patent Examiner
April 10, 2004

L. R. F. Smith
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